

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of



KOEBERL et al

Serial No. 10/761,530

Filed: January 21, 2004

Title: CONSTRUCTS FOR EXPRESSING LYSOSOMAL POLYPEPTIDES

Atty MJW-01579-1155  
Dkt.C# M#  
TC/A.U. 1652

Examiner: Patterson, Jr., C.

Date: March 19, 2007

ZFW  
9C

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

 **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment	0	minus highest number	
previously paid for	20	(at least 20) =	0 x \$50.00
			\$0.00 (1202)/\$0.00 (2202) \$

Independent claims after amendment	0	minus highest number	
previously paid for	3	(at least 3) =	0 x \$200.00
			\$0.00 (1201)/\$0.00 (2201) \$

If proper multiple dependent claims now added for first time, (ignore improper); add

\$360.00 (1203)/\$180.00 (2203) \$

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s)

One Month Extension	\$120.00 (1251)/\$60.00 (2251)
Two Month Extensions	\$450.00 (1252)/\$225.00 (2252)
Three Month Extensions	\$1020.00 (1253)/\$510.00 (2253)
Four Month Extensions	\$1590.00 (1254)/\$795.00 (2254)
Five Month Extensions	\$2160.00 (1255)/\$1080.00 (2255) \$

Terminal disclaimer enclosed, add		\$130.00 (1814)/ \$65.00 (2814) \$
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Applicant claims "small entity" status.     Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee		\$180.00 (1806) \$ 180.00
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Assignment Recording Fee		\$40.00 (8021) \$ 0.00
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Other:		\$ 0.00
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**TOTAL FEE (CREDIT CARD PAYMENT FORM ATTACHED) \$ 180.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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MJW:tat

NIXON & VANDERHYE P.C.  
By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of Confirmation No. 3856  
KOEBERL et al Atty. Ref.: 01579-1155  
Serial No. 10/761,530 Group: 1652  
Filed: January 21, 2004 Examiner: Patterson, Jr., C.  
For: CONSTRUCTS FOR EXPRESSING LYSOSOMAL  
POLYPEPTIDES

\* \* \* \* \*

Commissioner for Patents March 19, 2007  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

1. **PTO/SB/08a Pursuant to 37 CFR 1.97(b)**  
[within 3 months of filing or prior to 1st Office Action on the merits] N/C
- 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)] N/C
- 2 .(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)] \$180.00
3. **Pursuant to 37 CFR 1.97(d)**  
[after Final Office Action or Allowance (requires Rule 97(e)  
Statement and Rule 17(p) fee), but before final fee payment]  
\$180.00

The following are submitted in the above-identified application in compliance with  
37 C.F.R. §§ 1.97 and 1.98:

03/28/2007 SZEWIDIE1 00000091 10761530

4. A list of documents on Form PTO/SB/08a <sup>37 CFR 1.98(c)</sup> together with copies (as  
may be required) of each identified document and a translation or a  
concise explanation of each non-English language document (such  
as a Search Report) is enclosed herewith. 180.00 OP

This paper is submitted in accordance with:

- 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
  - a) The required Statement made in item 8 below; or
  - b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
  - a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
  - b) The required Statement is stated in item 8 below.
- 8. Statement under 37 CFR 1.97(e)
  - a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or

- b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,  
NIXON & VANDERHYE P.C.

By: Mary J. Wilson  
Mary J. Wilson  
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Sheet 1 of 3



**Atty. Docket No.**

**Serial No.**

01579-1155

10/761,530

**Applicant**

KOEBERL et al

**Filing Date**

TC/A.U.

**(Use several sheets if necessary)**

January 21, 2004

1652

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

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## **TRANSLATION**

\*Examiner \_\_\_\_\_ Date Considered \_\_\_\_\_

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Sheet 2 of 3

**INFORMATION DISCLOSURE  
CITATION**

(Use several sheets if necessary)

Atty. Docket No.	Serial No.
<b>01579-1155</b>	<b>10/761,530</b>
Applicant	
<b>KOEBERL et al</b>	
Filing Date	TC/A.U.
<b>January 21, 2004</b>	<b>1652</b>

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

Sun et al, "Enhanced Efficacy of an AAV Vector Encoding Chimeric, Highly Secreted Acid $\alpha$ -Glucosidase in Glycogen Storage Disease Type II", Molecular Therapy 14(6):822-830 (2006)
GenBank Accession No. NM_000477
Xia et al, "The HIV Tat protein transduction domain improves the biodistribution of $\beta$ -glucuronidase expressed from recombinant viral vectors", Nature Biotechnology 19:640-644 (2001)
Orii et al, "Defining the Pathway for Tat-mediated Delivery of $\beta$ -Glucuronidase in Cultured Cells and MPS VII Mice", Molecular Therapy 12(2):345-352 (2005)
Poenaru, L., Approach to Gene Therapy of Glycogenosis Type II (Pompe Disease), Molecular Genetics and Metabolism, 70 (3):163-169 (2000)
Hirschhorn, R., "Glycogen Storage Disease Type II: Acid .alpha.-Glucosidase (Acid Maltase) Deficiency", The Metabolic and Molecular Bases of Inherited Disease, (77) 11:2443-2464 (1995)
Barton, N.W., et al., "Therapeutic response to intravenous infusions of glucocerebrosidase in a patient with Gaucher disease", Proc. Natl. Acad. Sci, 87:1913-1916 (Mar. 1990)
Lauer, R.M., "Administration of a Mixture of Fungal Glucosidases to a Patient with Type II Glycogenosis (Pompe's Disease)", Pediatrics, 42:672-676 (1968)
Van den Hout., et al., "Enzyme therapy for Pompe disease with recombinant human .alpha.-glucosidase from rabbit milk", J. Inherit. Metab. Dis., 24:266-274 (2001)
Williams, J.C., et al., "Enzyme Replacement in Pompe Disease With an .alpha.-Glucosidase-Low Density Lipoprotein Complex*", Birth Defects: Original Article Series, 16 (1):415-423 (1980)
Yang, H.W., et al., "Recombinant Human Acid .alpha.-Glucosidase Corrects Acid .alpha.-Glucosidase-Deficient Human Fibroblasts, Quail Fibroblasts, and Quail Myoblasts", Pediatric Research, 43 (3):374-380 (1998)
Amalfitano, A., et al., "Recombinant human acid .alpha.-glucosidase enzyme therapy for infantile glycogen storage disease type II: Results of a phase I/II clinical trial", Genetics in Medicine, 3 (2):132-138 (2001)
Ausems, M., et al., "Frequency of glycogen storage disease type II in The Netherlands: implications for diagnosis and genetic counselling", European Journal of Human Genetics, 7:713-716 (1999)
Bijvoet, A.G.A., et al., "Recombinant human acid .alpha.-glucosidase: high level production in mouse milk, biochemical characteristics, correction of enzyme deficiency in GSDII KO mice", Human Molecular Genetics, 7 (11):1815-1824 (1998)
Bijvoet, A.G.A., et al., "Human acid .alpha.-glucosidase from rabbit milk has therapeutic effect in mice with glycogen storage disease type II", Human Molecular Genetics, 8 (12):2145-2153 (1999)
Brooks, D.A., "Immune Response to Enzyme Replacement Therapy in Lysosomal Storage Disorder Patients and Animal Models", Molecular Genetics and Metabolism, 68:268-275 (1999)
de Barsy, T., et al., "Enzyme Replacement in Pompe Disease: An Attempt with Purified Human Acid .alpha.-Glucosidase*", Birth Defects:Original Article Series, 9 (2):184-190 (1973)
Fuller, M., et al., "Isolation and characterisation of a recombinant, precursor form of lysosomal acid .alpha.-glucosidase", Eur. J. Biochem, 234:903-909 (1995)
Hermans, M.M.P., et al., "The effect of a single base pair deletion (.DELTA.T525) and a C1634T missense mutation (pro545leu) on the expression of lysosomal .alpha.-glucosidase in patients with glycogen storage disease type II", Human Molecular Genetics, 3 (12):2213-2218 (1994)
Hermans, M.M.P., et al., "The conservative substitution Asp-645.fwdarw.Glu in lysosomal .alpha.-glucosidase affects transport and phosphorylation of the enzyme in an adult patient with glycogen-storage disease type II", Biochem. J., 289:687-693 (1993)
Hermans, M.M.P., et al., "Identification of a Point Mutation in the Human Lysosomal .alpha.-Glucosidase Gene Causing Infantile Glycogenosis Type II", Biochemical and Biophysical Research Communications, 179 (2):919-926 (1991)

\*Examiner

Date Considered

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Sheet 3 of 3

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